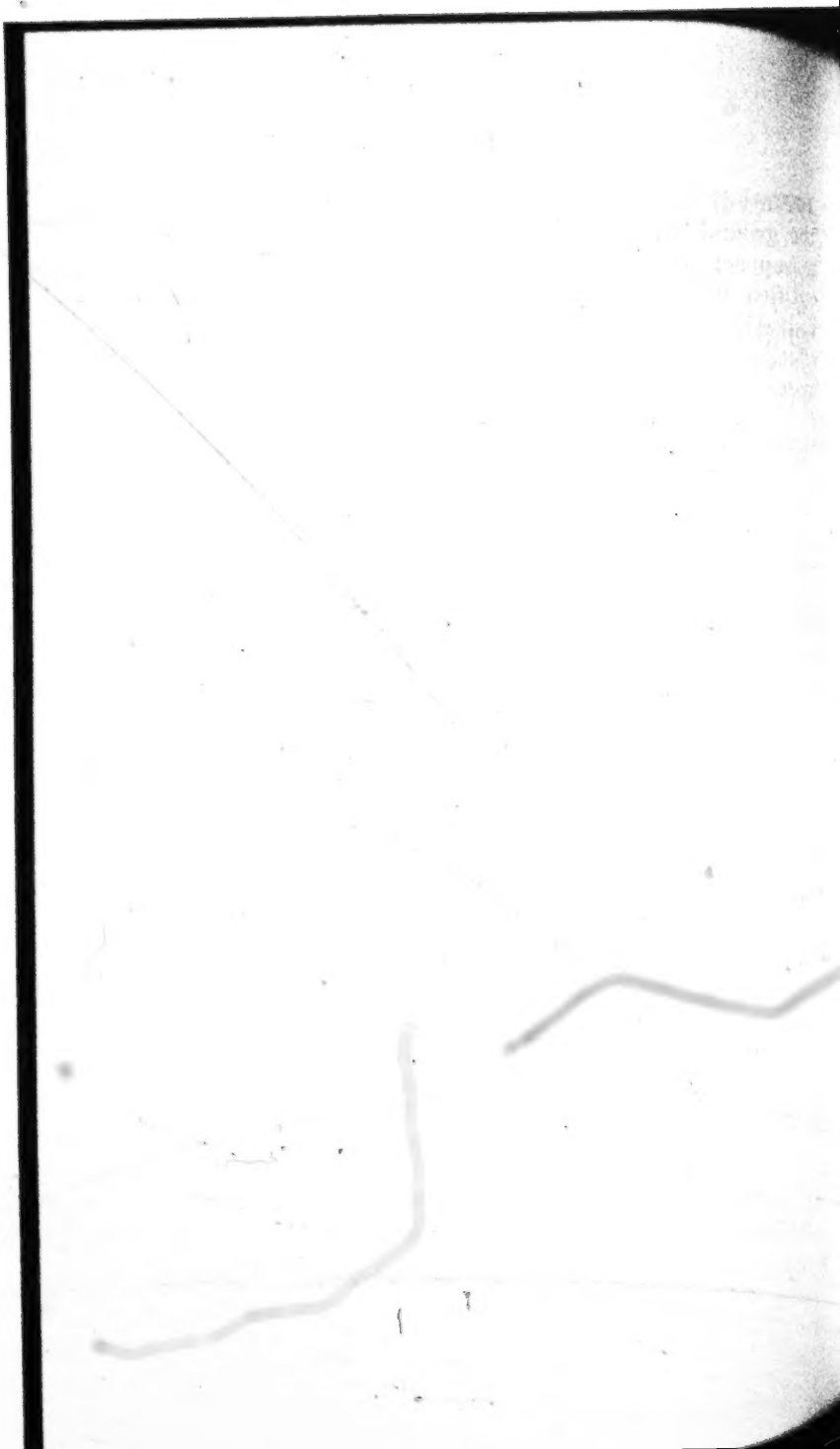

IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-528

CIBA CORPORATION, a corporation of the State of Delaware,

Petitioner,

vs.

ELLIOTT L. RICHARDSON, Secretary of Health, Education and Welfare and DR. CHARLES C. EDWARDS, Commissioner of Food and Drugs,

Respondents.

BRIEF FOR THE PETITIONER

CLYDE A. SZUCH
Attorney for Petitioner
570 Broad Street
Newark, N J. 07102

Of Counsel:

PITNEY, HARDIN & KIPP
MICHAEL E. RODGERS
RICHARD BARTH
HUGH A. D'ANDRADE

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BRIEF FOR THE PETITIONER

Opinions Below

The opinion of the Court of Appeals appears at 463 F.2d 225 (3rd Cir. 1972) and in the appendix at p. 215. The oral opinion of the District Court is set forth in the appendix at pp. 208-14.

Jurisdiction

The judgment and opinion of the Court of Appeals were entered on June 5, 1972. By order signed by Justice Rhenquist of this Court dated September 1, 1972, the time for filing a petition for a writ of certiorari herein was extended

to October 2, 1972, and the petition was filed on that date and granted on January 8, 1973. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

Statute Involved

The statute involved is the Food, Drug and Cosmetic Act of 1938, as amended, 21 U.S.C. § 301 *et seq.* The pertinent sections of that Act are set forth in the appendix at p. 475.

Question Presented

Do the Federal district courts have exclusive jurisdiction to adjudicate whether a drug is a "new drug" as defined in the Food, Drug and Cosmetic Act of 1938, as amended, and therefore subject to the regulatory procedures applicable to such drugs?

Statement of the Case

The Federal Food, Drug and Cosmetic Act of 1938,[1] as amended (the "Act"), prohibits the shipment in interstate commerce of any "new drug" not covered by an approved New Drug Application. Approval of a New Drug Application is granted or denied by the Food and Drug Administration (the "FDA") on the basis of information submitted by the manufacturer in the New Drug Application. Under the Act, the New Drug Application is approved upon a showing that the "new drug" is safe and effective for the conditions of use recommended or prescribed in its labeling.

Not all drugs, however, require an approved New Drug Application for marketing. Only if a drug is not generally

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[1] 21 U.S.C. § 301 *et seq.*

recognized as safe and effective for the conditions of use recommended or prescribed in its labeling is it a "new drug" and thus required to be covered by an approved New Drug Application.

Prior to 1962 a drug was a "new drug" only if not generally recognized as safe, and a manufacturer's New Drug Application was only required to contain evidence of the drug's safety. The amendments to the Act in 1962[2] changed the definition of "new drug" to encompass drugs not generally recognized as safe and *effective,* and added to the grounds for New Drug Application approval the requirement of the production of evidence of the effectiveness of a "new drug" as well as of its safety. Because of this new requirement, the FDA contracted the National Academy of Sciences-National Research Council (the "NAS-NRC") for the review of drugs subject to New Drugs Applications prior to 1962 to determine whether there existed for such drugs the requisite evidence of their effectiveness.

A New Drug Application for Ritonic, the drug which is the subject of this action, became effective on January 12, 1958, based upon proof of safety. On September 12, 1969, the FDA notified petitioner of its intention to withdraw the approval of the Ritonic New Drug Application on the grounds that the NAS-NRC review of Ritonic had concluded that there was not substantial evidence of its effectiveness and requested the submission of additional evidence of its efficacy.[3] By letter dated October 10, 1969, petitioner indicated its disagreement with the NAS-NRC conclusion of lack of substantial evidence that Ritonic is effective. In addition petitioner expressly reserved its right to assert that Ritonic was not a "new drug" and therefore not subject to the New Drug Application approval requirements of the Act.[4]

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[2] 76 Stat. 780 (1962).

[3] Appendix p. 199.

[4] Appendix p. 202.

Before any action was taken to withdraw the FDA's approval of Ritonic, the Pharmaceutical Manufacturers Association filed a suit challenging the validity of the regulations establishing the procedures to be followed in determining the efficacy of drug products. That action was determined adversely to the FDA on January 16, 1970, *Pharmaceutical Manufacturers Association* v. *Finch*, 307 F.Supp. 858 (D.Del. 1970), and on May 8, 1970, the FDA repromulgated the regulations.[5]

On August 5, 1970, the FDA issued a formal notice of its intention to withdraw its approval of the New Drug Application for Ritonic pursuant to the new regulations.[6] That notice afforded petitioner an opportunity to request a hearing to show substantial evidence of the safety and efficacy of the product. By letter dated August 31, 1970,[7] petitioner requested a hearing but indicated its disagreement with the regulation of the FDA pursuant to which it sought to require petitioner to state reasons why the New Drug Application should not be withdrawn as a precondition to a hearing.[8] Petitioner again reserved its right to maintain that the product in issue was not a new drug.[9]

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[5] 21 C.F.R. §§ 130.12, 130.14.

[6] Appendix p. 203.

[7] Appendix p. 206.

[8] This position was based on the arguments being advanced in the courts by the PMA in an action against the FDA. That action was decided adversely to PMA on October 20, 1970, *Pharmaceutical Manufacturers Association* v. *Elliott L. Richardson*, 318 F.Supp. 301 (D.Del. 1970).

[9] Petitioner stated in its response:

> "We wish to advise you that it is CIBA's position that Ritonic Capsules are not now a new drug under the Food, Drug and Cosmetic Act, as amended and that the amendments of 1962 are not applicable to that drug. Therefore, this election to avail ourselves of the opportunity for a Hearing is made with a reservation of the right to establish these facts in the administrative proceedings, or in judicial proceedings, or both."

On September 4, 1970, this action was instituted. Several weeks later the FDA published a notice withdrawing its approval of the New Drug Application for Ritonic[10] without addressing itself to petitioner's position that Ritonic was not a "new drug."

As a result of the denial of the requested hearing and because there was no appellate decision considering and sustaining the validity of the republished regulations, petitioner filed a direct appeal under Section 505(h) of the Act. In that appeal petitioner challenged the right of the FDA to condition the manufacturer's right to a hearing upon submission of evidence which it might consider to be substantial. The action of the FDA in this instance was affirmed. *Ciba-Geigy Corporation* v. *Richardson,* 446 F.2d 466 (2nd Cir. 1971). That appeal did not, and, for reasons set out hereinafter, could not have considered whether Ritonic is a "new drug."

The FDA moved to dismiss the complaint in this case on the ground, *inter alia,* that the FDA, not the courts, has exclusive jurisdiction to determine whether a drug is a "new drug" and that a manufacturer's only avenue of judicial redress from an FDA determination on this point is by appeal to a circuit court of appeals By stipulation of the parties, this jurisdictional question was the sole issue briefed or argued in the district court.

The district court dismissed the action on the ground that even if that court had jurisdiction it would exercise its discretion and refuse to determine whether Ritonic was a "new drug" in a declaratory judgment action.[11] The Third Circuit Court of Appeals affirmed the dismissal on the ground that the FDA has primary jurisdicton to adjudicate whether a drug is a "new drug" and that the FDA

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[10] Appendix p. 207.

[11] Transcript of Oral Argument, Appendix pps. 208-14.

properly exercised that jurisdiction in its administrative proceeding withdrawing the New Drug Application previously in effect for Ritonic.

ARGUMENT

The District Court Has Sole Jurisdiction To Adjudicate Whether a Drug Is a "New Drug" Within the Meaning of the Act.

The Act provides that before a manufacturer may ship a "new drug" in interstate commerce it must obtain FDA approval of a New Drug Application for that drug.[12] The FDA is instructed to issue an order denying approval of a New Drug Application[13] or withdrawing approval previously granted[14] if the Commissioner concludes that there is a lack of "substantial evidence" that the drug involved is safe and effective for the conditions of use prescribed or recommended in its labeling.

"Substantial evidence" is a term of art referring to particular types of scientific evidence set out in the Act and the regulations promulgated thereunder.[15] In essence, "substantial evidence" involves the results of "adequate and well-controlled clinical investigations by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."

Before issuing an order denying or withdrawing its approval of a New Drug Application, the FDA must give a manufacturer notice and opportunity for an adminis-

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[12] Act § 301(d) which incorporates by reference § 505(a); 21 U.S.C. 331(d), 355(a); Appendix pps. 475, 478.

[13] Act § 505(d); 21 U.S.C. 355(d); Appendix p. 478.

[14] Act § 505(e); 21 U.S.C. 355(e); Appendix p. 479.

[15] Act § 505(d); 21 U.S.C. 355(d); Appendix p. 478; 21 C.F.R., Part 130, § 130.12.

trative hearing.[16] After final FDA action denying or withdrawing approval of a New Drug Application, a manufacturer is entitled to seek a review of the FDA's action in an appropriate court of appeals.[17]

Not all drugs, however, are required to have an approved New Drug Application before they can be marketed; only "new drugs" must follow this procedure. The term "new drug" is also a term of art defined in the Act.[18] In essence a "new drug" is any drug which is not generally recognized by experts qualified to evaluate the safety and effectiveness of drugs as being safe and effective for the conditions of use recommended in its labeling or any drug which is so recognized but which has not been used to a material extent or for a material time for the conditions recommended in its labeling.

The distinction between whether a drug is a "new drug", i.e., not generally recognized as safe and effective, and required to have a New Drug Application, and whether a "new drug" has been demonstrated by "substantial evidence" to be safe and effective and therefore entitled to approval of its New Drug Application is part of the basic structure of the Act. If a drug has been in use by the medical profession for a material time and to a material extent and if, through such use, has become generally recognized as being safe and effective, then the drug is no longer a "new drug" and the manufacturer may market it without first obtaining an approved New Drug Application.

Respondents do not dispute that drugs which are not "new drugs" may be legally marketed without an approved New Drug Application; they argue, instead, that the FDA

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[16] Act §§ 505(d); 505(e); 21 U.S.C. 355(d); 355(e); Appendix pps. 478-479.

[17] Act § 505(h); 21 U.S.C. 355(h); Appendix p. 480.

[18] Act § 201(p); 21 U.S.C. 321(p); Appendix pps. 482-83.

rather than the district courts has jurisdiction of the "new drug" question. They contend that, when the FDA has made a determination of this question in connection with the withdrawal of a New Drug Application, the only judicial remedy is an appeal from its action to an appropriate court of appeals. Respondents do not and cannot, however, point to anything in the Act granting the FDA the jurisdiction claimed.

Section 505 of the Act, the section establishing power in the FDA to regulate "new drugs", particularly parts (d) and (e) thereof, states that if, after notice and opportunity for a hearing, the Commissioner determines that a New Drug Application does not contain adequate proof of safety and effectiveness, he shall "issue an order refusing to approve the application" or "withdraw approval of an application" granted previously.

Nowhere do sections 505(d) and (e) (or any other sections) authorize the Commissioner to adjudicate whether a drug has been in use for a material time and to a material extent or whether it is generally recognized as safe and effective. Neither does the Act empower the Commissioner to issue an order declaring the drug is or is not a "new drug". The administrative procedure which these sections create clearly contemplates only the adjudication of whether the tests for approval of a New Drug Application, i.e., "substantial evidence" of safety and effectiveness, have been met.

Further evidence of this clearly defined role of the FDA is found in Section 505(h) of the Act which specifies the limits of the review jurisdiction of the federal circuit courts. Section 505(h) provides for an appeal by a manufacturer from a determination in the administrative proceeding created by Sections 505(d) and (e) denying or withdrawing New Drug Application approval. The language of this section makes clear, however, that it does not

empower the circuit courts to review a finding that a drug is a "new drug." In pertinent part this section reads as follows:

> "(h) An appeal may be taken by the applicant from an order of the Secretary *refusing or withdrawing approval of an application* [for approval of a New Drug Application] under this section. Such appeal shall be taken by filing in the United States Court of Appeals . . . a written petition praying that the order of the Secretary [withdrawing or denying approval of the New Drug Application] be set aside." (Emphasis added)

This section only gives the circuit courts appellate jurisdiction over the Secretary's action refusing or withdrawing approval of a new drug application. The circuits courts, therefore, do not have appellate jurisdiction with respect to the "new drug" issue since, like an administrative agency, they have only that jurisdiction granted to them by statute. See *Turkel* v. *FDA*, 334 F.2d 844 (6th Cir. 1964), where the FDA argued, and the court held, that appellate jurisdiction is dependent wholly upon statute and the applicable statute, § 505(h) of the Act, only grants a right of appeal from the denial or withdrawal of a New Drug Application.

Although jurisdiction to adjudicate which drugs are "new drugs" is not given to the FDA, it is implicit from the Act that such jurisdiction does lie in the federal district courts. The Act creates severe penalties, including fining and imprisonment of a manufacturer's officers and seizure of its product in interstate commerce, if such manufacturer ships a "new drug" in interstate commerce without an approved New Drug Application.[19] For these penalties to be imposed, the FDA must institute appropriate proceed-

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[19] Act §§ 302, 303(a), 304(a); 21 U.S.C. 332, 333(a), 334(a); Appendix pps. 475-76.

ings in a federal district court and, in such proceeding, the manufacturer will be guilty of no offense if its drug is found to be not a "new drug."[20]

The district court's jurisdiction to adjudicate whether the drug involved is a "new drug" has been consistently recognized in enforcement proceeding cases for many years. The question adjudicated in these cases is not whether the drug is actually safe and effective, a question which would involve an analysis of scientific and medical evidence particularly within the competence of the FDA. Rather, the inquiry is what the consensus is among doctors and others in a positon to be familiar with the drug's safety and effectiveness. This issue is readily within the competence of the courts. See e.g., *Merritt Corp.* v. *Folsom*, 165 F.Supp. 418 (D.D.C. 1958); *U.S.* v. *345 Bulk Cartons . . . "Trim Reducing Aid Cigarettes"*, 178 F.Supp. 847 (D.N.J. 1959); *U.S.* v. *An Article of Drug . . . "Quinaglute,"* 268 F.Supp. 245 (E.D.Mo. 1967); *U.S.* v. *Articles of Drug . . . "Quick-O-Ver,"* 274 F.Supp. 443, 445-46 (D.Md. 1967); *U.S.* v. *An Article of Drug . . . "Line Away"*, 284 F.Supp. 107 (D.Del. 1968) affirmed other grounds 415 F.2d 369 (3rd Cir. 1969); *U.S.* v. *7 Cartons . . . "Ferro-Lac"*, 293 F.Supp. 660 (S.D. Ill. 1968) affirmed 424 F.2d 1364 (7th Cir. 1970); *U.S.* v. *An Article of Drug . . . "Furestrol"*, 294 F.Supp. 1307 (D.Ga. 1969) affirmed 415 F.2d 390 (5th Cir. 1969); *U. S.* v. *An Article of Drug . . . "Excedrin P.M."*, —— F.Supp. ——, CCH, Food Drug and Cosmetic Law Reporter, ¶ 40,486 (E.D.N.Y. 1971); *U.S.* v. *An Article of Drug . . . "Bentex Ulcerine," etc.*, —— F.Supp. —— (D.Tenn. 1972), affirmed —— F.2d ——, CCH, Food Drug and Cosmetic Law Reporter ¶ 40,771 (5th Cir. 1972). See also *U.S.* v. *Allan Drug Corp.*, 357 F.2d 713 (10th Cir. 1966).

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[20] Act § 301(d) incorporating by reference Section 505(a); Appendix pps. 475, 477.

Once it is established that the district courts have jurisdiction to determine the "new drug" issue in enforcement proceedings, it is axiomatic that they must also have jurisdiction to decide this issue in a declaratory judgment action instituted by a manufacturer. The only difference between the two actions is that in the declaratory action the manufacturer seeks to have its product's "new drug" status determined prior to being forced to incur the risk of being subject to criminal and seizure penalties if it does not prevail in the enforcement action. See *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 18 L.ed 2d 681 and *Gardner* v. *Toilet Goods Association*, 387 U.S. 167, 18 L.ed 2d 704 (1967). Jurisdiction of the "new drug" question has also been assumed by the courts in a number of recent declaratory judgment actions. See *e.g.*, *USV Pharmaceutical Corporation* v. *Richardson*, —— F.Supp. ——, CCH, Food Drug and Cosmetic Law Reporter ¶40,489 (E.D. Va. 1971), affirmed —— F.2d —— (4th Cir. 1972); *Lemmon Pharmacal Co.* v. *Elliott L. Richardson, et al.*, 319 F.Supp. 375 (E.D. Pa. 1970). See also *AMP, Inc.* v. *Gardner*, 389 F.2d 825 (2nd Cir. 1968), affirming 275 F.Supp. 410 (S.D.N.Y. 1967).

Not only is the decision of the court below that FDA has primary jurisdiction to adjudicate the "new drug" status of drugs devoid of statutory or judicial support, it also is contrary to the settled interpretation of the Act given to it by the FDA and the drug industry since its enactment in 1938. Petitioner knows of no instance in which the FDA has claimed jurisdiction of this question prior to the claims made in the briefs filed on its behalf in this and several similar actions commenced at approximately the same time.

From the series of notices issued by the FDA prior to its withdrawal of the Ritonic New Drug Application, it is clear that the Agency even then did not contemplate taking evidence or granting a hearing on the "new drug" status of Ritonic. The initial notice of the results of the NAS-NRC

report on Ritonic invited Ciba to submit evidence bearing on why the New Drug Application should not be withdrawn. It stated that "the only material which will be considered acceptable for review must be well organized and consist of adequate and well-controlled studies bearing on the efficacy of the products and not previously submitted." That is, the only acceptable submission would be "substantial evidence" in support of the drug's effectiveness and bearing on the question whether or not to withdraw the New Drug Application, not evidence as to the general recognition of the drug's effectiveness. Similarly, the notice of opportunity for a hearing only contemplated a hearing on the question of the withdrawal of the New Drug Application and conditioned the right to that hearing on the presentation of the "clinical and other investigational data" Ciba was prepared to prove in support of its New Drug Application.

Further evidence of the FDA's previous (and possibly current) view on this question is the fact that it has never attempted to promulgate regulations dealing with the type of evidence acceptable for a determination of a drug's "new drug" status or the criteria for obtaining a hearing on this issue. This omission is all the more significant since the FDA promulgated regulations in September of 1969 and again in May of 1970[21] setting out the types of evidence and the hearing procedures applicable in connection with the withdrawal of New Drug Applications.

It is a fundamental principle of statutory interpretation that a continuous interpretation of a statute by the parties which it affects, and particularly by the executive agency created to implement it, will be given great weight in the interpretation of that statute and not overturned in the

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[21] 21 C.F.R. §§ 130.12, 130.14.

absence of cogent reasons therefore. See *e.g., United States* v. *Midwest Oil Co.*, 236 U.S. 459, 472-473, 59 L.ed. 2d 673, 681 (1915); *McLaren* v. *Fleischer*, 256 U.S. 477, 480-481, 65 L.ed. 1052, 1053 (1921); *Bowles* v. *Seminole Rock Co.*, 325 U.S. 410, 413-414, 89 L.ed. 1700, 1702 (1945); *Power Reactor Co.* v. *International Union of Electrical, etc.*, 367 U.S. 396, 408, 6 L.ed. 2d 924, 932 (1961); 82 C.J.S., Statutes § 359; 2 Sutherland, *Statutes and Statutory Construction*, (1943) § 5105. In *Midwest Oil Co., supra*, this Court stated that this presumption is

> "the basis of a wise and quieting rule that, in determining the meaning of a statute or the existence of a power, weight shall be given to the usage itself,—even when the validity of the practice is the subject of investigation."

In sharp contrast to the conclusion of the court below, the Court of Appeals for the Fourth Circuit, in *Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363, (4th Cir. 1972), appendix p. 258, in a carefully reasoned opinion has rejected the argument of the FDA advanced below and concluded that the FDA is without jurisdiction to adjudicate whether a drug is a "new drug."

The *Bentex* case, like the instant one, was a declaratory judgment action commenced by a manufacturer seeking a determination that its product was not a "new drug." The manufacturer in *Bentex*, like Ciba, acted after receiving notice from the FDA that it had determined its product to be a "new drug" which lacked an approved New Drug Application and which would be subject to FDA instituted enforcement proceedings if not withdrawn from the market. In *Bentex* the FDA argued, as it did below, that it, rather than the courts, has primary jurisdiction to adjudicate the "new drug" status of drugs.

The Fourth Circuit recognized that the questions of whether to grant approval of a New Drug Application and

whether a drug is a "new drug" are wholly sepa
distinct. After an analysis of the Act, it held th
was no basis for concluding that the FDA had juri
to adjudicate the latter question or that the co
appeals would have jurisdiction on appeal to revie
determination if it were made.

It is submitted that the conclusion reached by the
Circuit is consistent with the language of the A
judicial and historic administrative interpretatio
manufacturers are entitled to an impartial judicial
for an adjudication of the "new drug" question.

CONCLUSION

For the foregoing reasons it is respectfully sub
that the opinion and judgment of the Third Circuit
of Appeals should be reversed and that this matter
be remanded to the district court for a determinat
whether Ritonic is a "new drug".

Respectfully submitted,

CLYDE A. SZUCH
Attorney for Peti
570 Broad Street
Newark, N. J. 0710

Dated: March 1, 1973.

Of Counsel:

PITNEY, HARDIN & KIPP
MICHAEL E. RODGERS
RICHARD BARTH
HUGH A. D'ANDRADE